

4X MEDICATED TOOTHACHE AND GUM CREAM- benzocaine cream

Lornamead

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

8015601 4x Med Cream

Benzalkonium chloride 0.13% . . . Oral antiseptic

Benzocaine 20% . . . Oral pain reliever

Menthol 0.5% . . . Oral pain reliever

Zinc chloride 0.15% . . . Oral astringent

Use

for the temporary relief of pain due to toothaches * to help protect against infection of minor oral irritation

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops: * pale, gray, or blue colored skin (cyanosis) * headache * rapid heart rate * shortness of breath * dizziness or lightheadedness * fatigue or lack of energy

Allergy alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or other "caine" anesthetics

Do not use * more than directed * for more than 7 days unless told to do so by a dentist or doctor * for teething * in children under 2 years of age

Stop use and ask a doctor if * swelling, rash or fever develops * irritation, pain or redness persists or worsens * symptoms do not improve in 7 days * allergic reaction occurs

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

cut open tip of tube on score mark * adults and children 2 years of age and older: apply a small amount of product to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor * children under 12 years of age should be supervised in the use of this product * children under 2 years of age: do not use

do not use if tip is cut prior to opening * this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted * do not continuously * this formula will stay in place for extended duration of relief * avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, titanium dioxide



LORNAMEAD, INC.		PROJECT INFO PRODUCTION NOTES	
DATE:	DECEMBER 31, 2019	<div> <div>CYAN</div> <div>MAGENTA</div> <div>YELLOW</div> <div>BLACK</div> </div> <div> <div>WHITE</div> <div>PMS 200</div> <div></div> <div></div> </div>	<div>APPROVALS</div> <div>CREATIVE _____</div> <div>MARKETING _____</div> <div>R&D _____</div> <div>QUALITY _____</div> <div>PURCHASING _____</div> <div>CEO _____</div>
PROJECT:	CVS 4X MEDICATED TOOTHACHE CREAM CARTON		
ITEM #:	2821601R1		
DIELINE #:	5180906		
SIZE:	1.000" X 1.000" X 4.313"		
FILE NAME:	CVS_4XMEDICATED_TOOTHACHECREAM_CTN_2821601R1-DLJM		
PRINTER:	MODPAC		
NOTE(S):			

4X MEDICATED TOOTHACHE AND GUM CREAM				
benzocaine cream				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62721-5601	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.13 g in 100 g	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	20 g in 100 g	
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	0.15 g in 100 g	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	0.25 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
SORBIC ACID (UNII: X045WJ989B)				
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (Cloudy White)	Score		
Shape		Size		
Flavor	WINTERGREEN	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62721-5601-9	9.4 g in 1 TUBE; Type 0: Not a Combination Product	06/05/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	06/05/2020		

Labeler - Lornamead (126440440)

Registrant - Lornamead (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(62721-5601)